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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,146	11/15/2001	Leif Ostergaard	0459-0651P	6240

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EXAMINER

ROY, BAISAKHI

ART UNIT PAPER NUMBER

3737

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,146

Applicant(s)

OSTERGAARD, LEIF

Examiner

Baisakhi Roy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-61 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 31-61 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/21/01, 1/10/02</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 53 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 53 and 55 are system claims which are dependent on previous method claims and should be modified to be in independent form or dependent on a system claim.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 31-34, 36-48, 50-52, 56, 58, and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Kupfer et al. (5287273). Kupfer et al. disclose a method for determining the physical aspects of blood circulation with the bolus injection of a tracer dose such as Gd-DTPA to an organ or tissue of a mammal, determining a time series of the concentration data being indicative of the concentration of the tracer in the blood circulation, performing deconvolution of the time series of the tomographic and concentration data to determine residue function, and determining distribution of transit

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times from the residue function (abstract, col. 3 lines 50-68, col. 4 lines 1-33, col. 5 lines 29-68, col. 6 lines 1-4 lines 53-68, col. 7 lines 1-14). Kupfer et al. further teach determining the density or amount of a normalized haemodynamic index from the distribution of transit times and comparing the determined density to a previously determined reference density (col. 6 lines 5-68, col. 7 lines 1-14). The reference teaches applying said method to cerebral and renal tissue and where the tomographic data is obtained by means of contrast magnetic resonance imaging (col. 5 lines 53-63). Kupfer et al. further teach said data containing information pertaining to subregions of sections of the tissue of interest where the haemodynamic indices are determined for said regions (col. 19 lines 41-49). The reference teaches obtaining information to prepare a reference table for depicting a treatment schedule (table 1).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kupfer et al. in view of Tatton (5783606). Kupfer et al. teach comparing the density or amount of contrast agent to a reference amount but do not teach the use of the Kolmogorov Smirnov test. It is well known in the art to use the Kolmogorov-Smirnov test (KS-test) to determine if two datasets differ significantly as disclosed by Tatton to determine the

changes in distribution of the tracer administered to a patient. It would have therefore been obvious to one of ordinary skill in the art to use the KS-test teaching by Tatton to modify the teaching by Kupfer et al. for the purpose of comparing widely distributed data pertaining to the distribution of the tracer.

5. Claims 49, 54, 57, 59, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kupfer et al. in view of Drane (5377681). Kupfer et al. teach obtaining information regarding blood circulation with the use of contrast agents but do not teach said contrast agent to be iron oxide particles evaluating the efficacy of a drug or a substance on the region of interest and obtaining information on the progression of a disease. In the same field of endeavor, Drane discloses a method of diagnosing impaired blood flow with the use of various contrast agents such as iron oxide particles, screening progression of a disease, determining the effects of various drugs on a tissue of interest, and preparing a reference table of the treatment schedule (col. 7 lines 51-57, col. 8 lines 1-4 lines 30-38, table 1). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Drane to modify the teaching by Kupfer et al. for the purpose of screening the progression of a disease and evaluating the effect of drugs on a region or tissue of interest.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 for relevant references of interest.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Baisakhi Roy whose telephone number is 571-272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

b. l.

BR


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